



## Content validity of the NCCN-FACT Ovarian Symptom Index-18 (NFOSI-18) ☆



Sally E. Jensen <sup>a,b</sup>, Karen Kaiser <sup>a</sup>, Leilani Lacson <sup>a</sup>, Julian Schink <sup>c,d,1</sup>, David Cella <sup>a,c,\*</sup>

<sup>a</sup> Department of Medical Social Sciences, Northwestern University Feinberg School of Medicine, 633N. St. Clair 19th Floor, Chicago, IL 60611, United States

<sup>b</sup> Department of Surgery (Organ Transplantation), Northwestern University Feinberg School of Medicine, 676N. St. Clair 19th Floor, Chicago, IL 60611, United States

<sup>c</sup> Robert H. Lurie Comprehensive Cancer Center, Northwestern University Feinberg School of Medicine, 675N. St. Clair 21st Floor, Chicago, IL 60611, United States

<sup>d</sup> Department of Obstetrics and Gynecology, Northwestern University Feinberg School of Medicine, 250 E. Superior St., Suite 3-2303, Chicago, IL 60611, United States

### HIGHLIGHTS

- Participants found the NFOSI-18 understandable and fit for the purpose of measuring their symptoms and concerns.
- Women most frequently mentioned fatigue, nausea, and neuropathy as their most bothersome side effects.
- Half the sample viewed fatigue and lack of energy as synonymous; others differentiated them to some degree.

### ARTICLE INFO

#### Article history:

Received 26 September 2014

Accepted 1 December 2014

Available online 8 December 2014

#### Keywords:

Ovarian cancer

Symptom index

Content validity

Quality of life

Patient-reported outcome

### ABSTRACT

**Objective.** This study examined the content validity of the NCCN-FACT Ovarian Symptom Index-18 (NFOSI-18), an advanced ovarian cancer symptom index comprised of symptoms perceived as most important by clinical experts and women with advanced ovarian cancer.

**Methods.** Eighteen women with advanced ovarian cancer completed the NFOSI-18 and participated in cognitive interviews to assess: (a) the understandability of the NFOSI-18; and (b) the things patients have in mind when responding to the item, “I am bothered by side effects of treatment,” and (c) the interpretation patients place on items relating to fatigue and lack of energy. Interviews were recorded and transcribed for qualitative analysis.

**Results.** All but 2 (89%) participants indicated that each item was clear and understandable and the same proportion (89%) stated they were “very confident” or “confident” about providing accurate answers to all but one item. When responding to the item, “I am bothered by side effects of treatment,” fatigue, nausea, and neuropathy constituted the most frequently mentioned concerns. Among the participants who were asked, eight participants responded that “fatigue” and “lack of energy” were the same concept and nine responded they were different. Participants associated “fatigue” with tiredness and associated “lack of energy” with the inability to perform daily tasks and activities.

**Conclusions.** The findings support the content validity of the NFOSI-18. Item revisions, deletions or additions do not appear warranted. Future research can address the reliability and validity of the NFOSI-18 in clinical research.

© 2014 Elsevier Inc. All rights reserved.

### Introduction

Due to the lack of detectable early symptoms, over 60% of women with ovarian cancer present with advanced stage disease, which confers a 27% five-year relative survival rate [1]. Women with advanced disease face multiple disease and treatment symptoms (e.g., fatigue, pain, swelling, nausea, and vomiting), as well as the psychological burden of living with the disease. Given the limited curative options for these women and their treatment and disease burden, quality of life (QOL) constitutes an important clinical and research outcome [2].

The NCCN-FACT Ovarian Symptom Index-18 (NFOSI-18) was developed to provide a clinically meaningful symptom index for advanced

☆ **Funding Statement:** Support for the study was provided by Clovis Oncology, Inc. The content represents original work. Clovis Oncology, Inc. had no involvement in the study design; the collection, analysis and interpretation of data; the writing of the report; and the decision to submit the paper for publication.

\* Corresponding author at: Department of Medical Social Sciences, Northwestern University Feinberg School of Medicine, 633 N. St. Clair 19th Floor, Chicago, IL 60611, United States. Fax: +1 312 503 9800.

E-mail address: [d-cella@northwestern.edu](mailto:d-cella@northwestern.edu) (D. Cella).

<sup>1</sup> Present Address: Spectrum Health, 145 Michigan St. NE, Suite 6300, Grand Rapids, MI 49503, United States.

ovarian cancer [2]. To meet Food and Drug Administration (FDA) regulatory standards, the NFOSI-18 development process incorporated patient and expert input and priorities to ensure that the items included reflected the symptoms/concerns considered most important by patients and clinicians [2]. Three subscales (disease-related symptoms, treatment-related symptoms, and general function/well-being) comprise the resulting 18-item index, which demonstrated good preliminary validity and reliability [2].

Evidence supporting the ability of a patient-reported outcome measure to assess the concepts for which it is designed (content validity) remains a high priority for the FDA [3]. Cognitive debriefing interviews, which assess whether item content, response scales, and instructions are understood as intended, constitute an important step to demonstrating the content validity of a measure by assessing patients' understanding of items. Thus, as the next step in the NFOSI-18 validation process, this study utilized cognitive debriefing interviews with women with advanced ovarian cancer to examine the following three aims: (1) to assess patients' understanding of the NFOSI-18 item meanings; (2) to determine the specific side effects patients consider when answering the NFOSI-18 item: "I am bothered by side effects of treatment;" and (3) to assess the extent to which patients understand the items: "I have a lack of energy" and "I feel fatigued" as synonymous.

## Methods

### Design

The development of the NFOSI-18 was previously described [2,4]. In this cross-sectional study, 18 women with advanced ovarian cancer participated in cognitive debriefing interviews to further assess the content validity of the NFOSI-18. The study was approved by the Northwestern University Institutional Review Board.

### Participants

Eligible participants were recruited from the Robert H. Lurie Comprehensive Cancer Center and had a confirmed diagnosis of ovarian or fallopian tube cancer or primary peritoneal cancer (stage III to IV); had received at least one, but no more than four, prior treatment regimens; had an ECOG performance status of 0 to 2; were at least 18 years old; and were able to provide informed consent. Women who received more than four prior treatment regimens and those not fluent in English were ineligible. Participants currently receiving treatment were included, and were interviewed at any time point during their treatment regimen. All participants provided written informed consent.

### Cognitive debriefing interviews

Trained interviewers conducted in-person interviews using a protocol based on the work of Willis [5,6]. Participants first provided brief demographic information and completed a paper-and-pencil version of the NFOSI-18. Next, they responded to a series of questions designed to ascertain comprehension of each NFOSI-18 item: (1) "How would you say this question in your own words?" (2) "What does (term) mean to you?" (3) "Do you have any questions about how to answer this question?" (4) "Is everything clear and understandable?" (5) "How confident are you that you can provide an accurate answer to this question?" (6) "What kind of things did you think about when you answered the question?" For the items "I have a lack of energy" and "I feel fatigued," participants also responded to the question, "Do you think lack of energy is the same as fatigue, or do you think they are different things?" and were asked to describe how they did or did not differ. The cognitive interviews were audio-recorded and transcribed.

### Neuropathy assessment

Following the cognitive debriefing interview, patients completed the Functional Assessment of Cancer Therapy/Gynecologic Oncology Group-Neurotoxicity-12-item version (FACT-GOG NTX-12) [7]. The FACT-GOG NTX-12 was administered after the interview to avoid priming patients to think about neuropathy.

### Determination of sample size

To ensure that qualitative findings are representative, research must include key characteristics of the patient population thought to influence the outcomes of interest in the study sample, confirm that the concepts are adequately described by study participants, and bring participants into the study until no new themes are obtained. This point of redundancy is known as theoretical saturation [8]. Past research reveals that saturation often occurs within the first 12 interviews and basic elements for themes are sometimes present as early as six interviews [9]. Saturation was considered to have been reached when no new concepts emerged over three consecutive interviews.

### Data analysis

Interview transcripts were reviewed for accuracy. Data across interviews were reviewed for each study aim. For aim 1, the frequency of responses to questions about the understandability of items was calculated. Participants' comments about the items were reviewed and summarized to assess comprehension of each item.

For aim 2, responses to the questions: "What does the phrase, 'bothered by side effects of treatment' mean to you?" and "What kinds of things did you think about when you answered this question?" were reviewed. The frequency of all side effects and concerns mentioned by participants were computed. Responses to the FACT-GOG NTX-12 were calculated to determine which participants had experienced neuropathy. Responses to the question "What does the phrase, 'bothered by side effects of treatment' mean to you?" were then reviewed specifically among participants who experienced neuropathy to examine whether they reported neuropathy when responding to this question.

For aim 3, participants' responses to the items "I have a lack of energy" and "I feel fatigued" were reviewed and summarized to illustrate how patients conceptualized "lack of energy" and "fatigue" to determine whether those conceptualizations differed.

## Results

### Patient characteristics

Table 1 displays participant socio-demographic and clinical characteristics. Fifty-six percent of participants were currently receiving treatment, with a mean of three years since diagnosis. Seventy-two percent of participants had received more than one line of chemotherapy. Among participants currently receiving therapy ( $n = 10$ ), five patients were receiving therapies associated with neuropathy (i.e., carboplatin, cisplatin). All participants not currently on treatment ( $n = 8$ ) had previously received a therapy associated with neuropathy.

### Understandability of the NFOSI-18

For every NFOSI-18 item, at least 89% of participants indicated that they had no questions about how to answer the item, and that the item was clear and understandable (Table 2). Eighty-nine percent of participants indicated that they were either "very confident" or "confident" that they could provide an accurate answer to every item, with the exception of "I am bothered by side effects of treatment", for which 83% were "very confident" or "confident" about accurately answering. For the item "I am bothered by side effects of treatment,"

Download English Version:

<https://daneshyari.com/en/article/6184851>

Download Persian Version:

<https://daneshyari.com/article/6184851>

[Daneshyari.com](https://daneshyari.com)